wherein said crosslinked polymers, uncrosslinked polymers, talc and magnesium stearate are provided as a matrix.

02 8. **(twice amended)** The device of claim 1, wherein said device additionally comprises 0<95% by weight granulating and tableting aids.

9. **(thrice amended)** A controlled release pharmaceutical delivery device which provides sustained or pulsatile delivery of a selected pharmaceutically active substance for a predetermined period of time, said device comprising;

- about 1 to less than 50% by weight of a mixture of hydroxyethylcellulose and hydroxypropylmethyl cellulose;
- about 1 to 60% by weight of ethylcellulose;
- about 1 to 80% by weight of at least one Carbopol® resin;
- about 0<10% by weight of talc;
- about 0<10% by weight of magnesium stearate; and
- about 0<95% by weight granulating and tableting aids,

wherein said hydroxyethylcellulose, hydroxypropylmethyl cellulose, ethylcellulose, Carbopol resin, talc, magnesium stearate and granulating and tableting aid are provided as a matrix.

03 23. **(thrice amended)** A pharmaceutical composition comprising;

- about 1 to 80% by weight pharmaceutically active agent;
- about 1 to 50% by weight of polymers of acrylic acid crosslinked with polyalkenyl alcohols or divinyl alchohol; and
- about 1 to 75% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose; wherein said polymers of acrylic acid, hydroxyethyl cellulose and hydroxypropyl methylcellulose are provided as a matrix.

04 30. **(thrice amended)** A pharmaceutical composition comprising:

- about 1 to 80% pharmaceutically active agent;
- about 1 to 60% by weight of hydroxyethylcellulose;
- about 1 to 75% by weight of hydroxypropylmethyl cellulose;
- about 1 to 60% by weight of ethylcellulose;
- about 1 to 50% by weight of at least one Carbopol® resin;
- about 0< 10% by weight of talc;

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- about 0< 10% by weight of magnesium stearate; and
- about 0< 95% by weight granulating and tableting aids.

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32. **(twice amended)** A controlled release pharmaceutical delivery device which provides sustained or pulsatile delivery of a selected pharmaceutically active substance for a predetermined period of time, said device comprising;

- about 1-50% by weight polymers of acrylic acid crosslinked with polyalkenyl alcohols or divinyl alchohol;
- about 1 to 75% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose; wherein said polymers of acrylic acid, hydroxyethyl cellulose and hydroxypropyl methylcellulose are provided as a matrix;
- about 0.5 to 50% by weight of a coating material coating said matrix, said coating material comprising anionic polymers based on methacrylic acid and methacrylic acid esters or neutral methacrylic acid esters with trimethylammonioethyl methacrylate chloride or cellulose esters.

33. **(twice amended)** A pharmaceutical composition comprising;

- about 1 to 80% by weight pharmaceutically active agent;
- about 1 to 50% by weight polymers of acrylic acid crosslinked with polyalkenyl alcohols or divinyl alchohol;
- about 1 to 75% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose; wherein said polymers of acrylic acid, hydroxyethyl cellulose and hydroxypropyl methylcellulose are provided as a matrix; and
- about 0.5 to 50% by weight of a coating material coating said matrix, said coating material comprising anionic polymers based on methacrylic acid and methacrylic acid esters or neutral methacrylic acid esters with trimethylammonioethyl methacrylate chloride or cellulose esters.

Remarks

Claims 1, 4, 7-12, 23 and 28-33 are before the Examiner. Claims 1, 8, 9, 23, 30, 32 and 33 are amended. The claims have been amended in order not to include zero as the lower limitation for some of the ingredients recited therein and to further recite that the ingredients are provided together as a matrix. These amendments are supported by the

description for example on pages 4-6. The Examiner's remarks in the Office Action are addressed below.

Claim Rejections – U.S.C. 102(e)

The Examiner rejected claims 1, 4, 8, 23 and 29 under 35 USC 102(e) as being anticipated by Skinner (U.S. 6,210,710). Skinner discloses a composition which comprises an active agent and blends of HPC, EC or derivatives of HPC, EC or HEC with other polysaccharides and their derivatives (see column 2, lines 23-27 and lines 51-57, abstract). No where does Skinner teach a combination of HEC and HPMC and further together with acrylic acid polymers. Furthermore, Skinner does not teach a combination of HEC, HPMC, acrylic acid polymers, talc and magnesium stearate. As such, Skinner does not anticipate the noted claims.

Claim Rejections – U.S.C. 103(a)

The Examiner rejected claims 1-4, 7-12, 23 and 28-33 under 35 U.S.C. 103(a) as being unpatentable in view of Guley et al (U.S. Patent No. 4,309,405) and Jain et al., (U.S. Patent No. 4,610,870). The Examiner asserts that Guley teaches a composition comprising both water soluble and water insoluble polymers and in particular the use of plural water-soluble polymers, active agent and lactose. The Examiner also asserts that Jain teaches the equivalence of HPC and HEC in the core.

The Applicant's respectfully disagree with the Examiner. While Guley may teach mixtures of water soluble and insoluble polymers, of the mixtures he suggests, no where does he specifically teach the use of the combination of HEC and HPMC, and further these two water soluble polymers with acrylic acid polymers specifically crosslinked with polyalkenyl alcohols or divinyl alcohol. The Examiner admittedly asserts that Jain does not teach the use of HEC but rather asserts that HPC is equivalent to HEC. This is not the case. The Applicants have been able to demonstrate that cellulose derivatives are not interchangeable for the same very purpose, more specifically, hydroxypropylmethyl cellulose (HPMC), ethylcellulose, and hydroxyethyl cellulose are not interchangeable for the very same purpose. This is supported by the data in Tables 1 and 2 (attached hereto) and in Figure 1 (attached hereto).

The amount of drug released in 1 hour is 17% for HPMC, 60% for HEC and 88% for EC. It was also observed that EC tablets broke up in 30 minutes. The time taken for 70% of the drug (i.e., $T_{70\%}$) to be released was about 9 hours for HPMC, 4 hours for HEC and 30 minutes for EC. These results clearly indicate that HPMC, HEC and EC are not

interchangeable for the same very purpose. Therefore, it is the specific recited mixture of polymers claimed together and further with the talc and magnesium stearate that provide the device of the invention.

The combination of Guley and Jain does not specifically teach each and every limitation of the claims and therefore cannot render them obvious. Furthermore as stated supra, you cannot simply substitute one polymer for another because this leads to different properties of the resultant formulation.

Claims 1, 4, 7, 18, 23, 28, 29, 32 and 33 were also rejected under 35 U.S.C. 103(a) as being unpatentable over Skinner in view of Guley. Again, the Applicant's respectfully disagree with the Examiner. Skinner discloses a composition which comprises an active agent and blends of HPC, EC or derivatives of HPC, EC or HEC with other polysaccharides and their derivatives (see column 2, lines 23-27 and lines 51-57, abstract). Guley teaches using mixtures of water soluble and water insoluble polymers but nowhere recites the use of HEC, HPMC and polymers of acrylic acid crosslinked with polyalkenyl alcohols or divinyl alchohol. Thus the combination of these two references does not teach or suggest each and every limitation as provided in the independent claims and therefore cannot render the presently claimed invention obvious.

Based on these submissions, the Applicants respectfully request withdrawal of the rejection of the present claims.

Conclusions

For the reasons given above, Applicants respectfully request reconsideration of this application and timely allowance of the pending claims. Applicants submit that the pending claims are in condition for allowance.

Respectfully submitted,
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